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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,833	04/14/2005	Ken-ichi Yamakoshi	004476.00033	8095

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BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

LIN, JACK

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/508,833

Applicant(s)

YAMAKOSHI, KEN-ICHI

Examiner

Jack Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 24, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/16/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendments filed on November 24, 2006.
2. The objections to claims 1 and 2 for informalities are withdrawn in view of the amendments to the claims.
3. The rejections of claims 4-8 and 10-18 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments to the claims.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

5. Claim 21 is objected to because of the following informalities: It appears that claim 21 should depend from claim 20 and not claim 22. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mendelson et al. (US Patent 5,372,135). Mendelson et al. discloses the same invention including a light source for irradiating light containing plural wavelengths (column 4, lines 11-13), light detectors for detecting light transmitted through the living body (column 4, line 41), and a computer (column 4, lines 61-62) that serves as a spectrum analyzer (column 4, lines 61-62), a spectrum subtraction generator (column 4, lines 45-50), and a blood constituents predictor that outputs the concentration of blood constituents (column 4, lines 63-64). Mendelson et al. also discloses a

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method of using the blood constituents measuring instrument (column 4, lines 10-64). The device and method of Mendelson et al. uses an empirical calibration study for absolute calibration of the measurement (column 6, lines 39-44) along with a multivariate calibration (column 5, lines 14) which requires the comparison of unknown blood constituents with a plurality of sample spectrum obtained non-invasively from living bodies with known constituents.

Regarding Claims 2-4, 10-11, 16-18, 20-21, and 23-25, Mendelson et al. discloses using a multi-regression analyzing model (column 5, line 14) with data from samples having known blood constituent concentrations (column 6, lines 39-44). The multi-regression analyzing model includes PLS and PCR (column 5, lines 17-23). Blood inherently contains albumin in a concentration of 3.0 – 6.0 g/dl (see for example Evans et al., US Patent 5,571,723, column 2, lines 40-41). Additionally, blood inherently has different hematocrit values.

Regarding Claims 5-6 and 12-13, Mendelson et al. discloses using light having a wavelength band of 1100-2500 nm (column 6, line 24).

Regarding Claims 7-8 and 14-15, Mendelson et al. discloses using an active spectroscopy to separate light from the light source prior to transmitting through the body (column 4, lines 15-26).

Response to Arguments

7. Applicant's arguments to the rejection of claims 1-25 under 35 U.S.C. 102 (b) as being anticipated by Mendelson et al. have been fully considered but they are not persuasive.

Applicant argues that Mendelson et al. does not disclose comparing the spectrum subtraction

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obtained from a living body whose blood constituents are not known with a plurality of sample spectrum subtractions obtained non-invasively from a living body whose blood constituents are known and predicting the concentration of the unknown blood constituent through this comparison. However, Mendelson et al. does in fact disclose these elements. Mendelson et al. discloses correlating the features of a differential absorption spectra with different concentrations of glucose during an empirical calibration study in patients undergoing standard glucose tolerance test (column 6, lines 39-44). Further, Mendelson et al. discloses this calibration is processed through a multivariate calibration technique (column 5, line 14). Inherent in Mendelson et al.'s disclosure is that in order to calibrate the measurement, the calibration would require a non-invasive measurement of patients whose blood constituents are known. Therefore, the Mendelson et al. anticipates claims 1-25 and the rejection is hereby maintained.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
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ERIC F. WINAKUR
PRIMARY EXAMINER

